**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| **In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION** | **MDL No. 1456**<br>**Master File No. 01-12257-PBS**<br>**Subcategory Case No. 06-11337** |
| **THIS DOCUMENT RELATES TO:**<br><br>*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*,<br>Civil Action No. 03-11226-PBS | **Hon. Patti B. Saris** |

**DEFENDANT SANDOZ INC.'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT**

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Sandoz' Opening Motion[1] argued for summary judgment on two issues based on a common set of undisputed facts. More specifically, Sandoz showed that, from 1991 until 1997, California received directly from Sandoz the Average Manufacturer Price ("AMP") for each of Sandoz' drugs, which represents a federally-mandated measure of the net prices received by Sandoz for drugs sold directly or indirectly to the retail class of trade, and that California received essentially the same information throughout the relevant time period in the form of the Unit Rebate Amounts ("URAs") for each Sandoz drug. Sandoz' motion also relied on the facts in Defendants' Joint Motion regarding the extent of California's knowledge and understanding of generic drug pricing, and highlighted in particular certain portions of that record. These facts establish that California cannot prove *scienter*, an essential element of Plaintiffs' claim, because California was, at all relevant times, fully aware of the material facts relating to Sandoz' pricing practices. These facts also show that the three year limitations period of the California False Claims Act, CAL. GOV'T CODE § 12650, *et seq.*, (the "CFCA") applies to the claims against Sandoz, and not the ten year "from the date of the violation" provision, because California had

[1] Sandoz refers to the following documents throughout this brief:

- Defendant Sandoz Inc.'s Brief in Support of its Motion for Summary Judgment ("Sandoz' Opening Motion")
- Local Rule 56.1 Statement of Undisputed Facts in Support of Defendant Sandoz Inc.'s Motion for Summary Judgment ("Sandoz' Opening SOF")
- Plaintiffs' Brief in Opposition to Defendant Sandoz Inc.'s Motion for Summary Judgment ("Plaintiffs' Opposition")
- Defendants' Joint Brief in Support of Their Motion for Partial Summary Judgment ("Defendants' Joint Motion")
- Defendants' Joint Statement of Undisputed Material Facts in Support of Their Motions for Partial Summary Judgment ("Defendants' Joint SOF")
- Defendant Sandoz Inc.'s Reply in Support of Its Local Rule 56.1 Statement of Undisputed Facts ("Sandoz' Reply SOF")
- Sandoz' Responses to Plaintiffs' Separate Statement of Additional Undisputed Facts in Opposition to Sandoz Inc.'s Motion for Summary Judgment ("Sandoz' Response to Plaintiffs' Additional SOF")
- Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Dey, Inc., Dey, L.P., and Sandoz Inc.'s Reply in Support of their Local Rule 56.1 Statement of Undisputed Facts ("Joint Reply SOF")
- Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Dey, Inc., Dey, L.P., and Sandoz Inc.'s Local Rule 56.1 Statement in Opposition to Plaintiffs' Statement of Additional Undisputed Facts in Opposition to Defendants' Motions for Partial Summary Judgment ("Joint Response to Plaintiffs' Additional SOF")

substantial evidence regarding generic drug pricing, specific allegations from Ven-A-Care regarding alleged "AWP fraud," and specific evidence at the granular level regarding Sandoz' products, that should have put responsible government officials on notice to inquire about possible false claims in connection with Medicaid reimbursements for Sandoz' drugs. Consequently, since Sandoz was not named as a defendant in this action until August of 2002, California's claims relating to reimbursement payments made before August of 1999 are barred.

California's opposition fails to create any material fact or legal issues that would preclude summary judgment. In fact, California expressly concedes many of the salient facts asserted by Sandoz. For the others, it quibbles with trivial issues and seeks to divert the Court's attention with irrelevant matters. These efforts cannot manufacture genuine disputes over material facts. California otherwise seeks to avoid the impact of the factual record by myopically analyzing factual slivers and dismissing each as insufficient under the law. That approach, of course, is improper.

The unavoidable bottom line is that California had the facts showing the differences between compendia AWPs and average prices Sandoz received for its drugs, along with a host of other information, which generally and specifically disclosed Sandoz' practices and the so-called "mega spreads" California now claims were hidden from it. Consequently, Sandoz is entitled to summary judgment as a matter of law on *scienter* and the statute of limitations.

## ARGUMENT

### I. The Facts Show Sandoz Lacked the Requisite *Scienter* Under the CFCA

Sandoz is entitled to summary judgment because Plaintiffs cannot make the requisite showing under the CFCA that Sandoz (1) *knowingly* presented or caused to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval; or (2) *knowingly* made, used, or caused to be made or used a false record or

statement to get a false claim paid or approved by the state or by any political subdivision. CAL. GOV'T CODE § 12651 (1) - (2). Indeed, the law is clear: California cannot prove it was allegedly "deceived" of something it has known all along. *Am. Contract Servs. v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 864 (2001) (government's "knowledge [of a fraud] effectively negates the fraud or falsity required by the [CFCA]."); *see also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n.8 (5th Cir. 2003) ("Inevitably, the extent of the government's knowledge is also bound up with whether the claim itself was false."). Likewise, "government knowledge" vitiates the requisite *scienter* under the CFCA: "there cannot be a knowing presentation of a false claim for payment where the government is fully aware of the facts surrounding the claim and approves it." *United States v. Shasta Servs. Inc.*, 440 F. Supp. 2d 1108, 1113 (E.D. Cal. 2006).

California admits, or fails to properly dispute and thus must be deemed to have admitted, the material facts that negate *scienter* under the CFCA. Specifically, California does not dispute that Sandoz directly provided it with AMP data for six years, from 1991 to 1997. *See* Sandoz' Reply SOF ¶¶ 12-13. California also does not dispute that AMP data represents a federally-mandated average, based on transactional information, of the net prices received by Sandoz for drugs sold directly or indirectly (*i.e.*, via wholesalers) to the retail class of trade. *See id.* ¶¶ 5-6. California further does not deny that it received Unit Rebate Amount ("URA") data for each Sandoz drug from the Center for Medicare and Medicaid Services ("CMS"). *See id.* ¶ 8. California could then use this URA data to calculate AMP information. *See id.* ¶ 9. Further, California considered AWP to be a more accurate reflection of transaction prices for drugs than AWP and other pricing indicators. *See id.* ¶ 7. These facts show that at a granular, drug specific level, California had the information to know and understand the magnitude of the differences between the AWPs and the AMPs for Sandoz drugs, directly for the period from 1991 to 1997,

and indirectly for the remaining time period at issue in this case. These differences include exactly the kinds of "mega-spreads" California claims were unknown to it. *See, e.g.*, Declaration of Joshua D. Weedman (hereinafter "Weedman Decl.") Ex. A (portions of table listing AWP, WAC, and AMP for Sandoz drugs for 1994 through 1996).[2]

Plaintiffs' Opposition likewise concedes the salient facts regarding the information known to California about the generic drug marketplace in general and the "spreads" in that marketplace between AWP and actual transaction prices:

- "In the mid to late 1980s, Plaintiff became aware through OIG reports that some providers could sometimes obtain prescription drugs at approximately 15% less than reported AWPs." *See* Plaintiffs' Opposition at 16.

- "[T]here might have been some general awareness [in the mid to late 1980s] that some AWPs were inflated to some degree." *See id.*

- The 1996 report from HHS-OIG entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services", (A-06-95-00062), "revealed that some providers could sometimes obtain some generic prescription drugs at a cost far less than the reported AWPs, resulting in an average pharmacist invoice price for generic drugs at 41.5 percent below AWP." *See id.*

- "[T]he 1998 *qui tam* complaint alerted the Attorney General to conduct of particular pharmaceutical manufacturers and of specific drug products." *See id.* at 17.

And California's own regulatory record shows it had contract pricing information for generic drugs as far back as 1988 showing the types of spreads it now claims were unknown. *See* Joint Reply SOF ¶ 26 (describing regulatory materials in support of amendment adopting FULs as a reimbursement measure, which materials included actual contract prices available to retail pharmacies in California on a host of generic drugs, a Sandoz (then called Geneva) price list showing AWP and WAC information, and an analysis of the "spreads" available to retail pharmacies on generic drugs and how that spread helped California lower its overall drug cost).

[2] Sandoz' expert report includes an exhibit with this information for each drug at issue, for the claimed damages period. That exhibit is 115 pages long, so only a portion is included here.

As explained in Sandoz' Opening Motion, under the relevant case law, these facts show California cannot establish that Sandoz acted with the *scienter* required for a CFCA claim. *See, e.g.*, Sandoz' Opening Motion at 9; *Mass. v. Mylan Labs.*, 608 F. Supp. 2d 127, 148-49 (D. Mass. 2008).

California's arguments to the contrary have no merit. First, California contends that Sandoz did not provide its AMPs to California from 1991 to 1997 "voluntarily." Whether voluntary or not, the undisputed, material fact is that California had Sandoz' AMPs for that time period, provided directly from Sandoz.[3]

Second, California argues it never used URAs to calculate AMPs, and never looked at AMPs for reimbursement purposes. Again, leaving aside California's misreading of the testimony, which shows California did in fact reverse-engineer AMPs from URAs, the material facts have been admitted. For the Sandoz drugs at issue, AMPs can easily be calculated from the URAs, which California admittedly had for all Sandoz drugs throughout the relevant time period. *See* Sandoz' Reply SOF ¶¶ 8-10.[4] And the salient fact remains that California had the AMP and URA information, and thus possessed the information about Sandoz it now claims it did not have.

Third, California contends that AMP data was confidential, and that it could only use AMP data for the calculation of rebates. Again, even accepting such statements as true, they are irrelevant. California was under no prohibition from comparing AMPs to AWPs, or from going so far as to use AMPs to set reimbursement rates, so long as each individual manufacturer and/or

[3] *See* Sandoz' Reply SOF ¶¶ 12-13 (explaining that, in any event, California's contention is unsupported by the cited testimony).

[4] California's point that four Sandoz drugs (only 8 out of 149 NDCs at issue) allegedly did not fit the usual model for Sandoz that would permit easy calculation of AMP from URA is so minor as to be insignificant for this motion. *See* Sandoz' Reply SOF ¶ 9.

wholesaler and its individual prices were not disclosed to third parties outside California Medicaid. *See* Joint Response to Plaintiffs' Additional SOF ¶ 26.

Fourth, California claims variously that AMPs were not "an accurate reflection of market prices," "would not be an accurate way of calculating the prices charged by manufacturers to consumers," and were a "poor basis for reimbursement because they were 'unreliable.'" California relies on materials from the Generic Pharmaceutical Association ("GPhA") for these "propositions," and claims that Sandoz is "disingenuous" when it argues that AMPs provided California "with 'knowledge' of market prices," while adhering to "GPhA's position regarding the unreliability of AMP." *See* Plaintiffs' Opposition at 8-9. California's Opposition misstates both Sandoz' arguments and the undisputed facts, which clearly support Sandoz' motion.

To begin with, California cannot dispute that, pursuant to federal law and the rebate contract signed by Sandoz and the federal government, between 1991 and 2004 AMPs represented a measure of the average prices Sandoz received for products distributed directly or indirectly through the retail class of trade. *See* Sandoz' Opening Motion at 6. Sandoz' opening brief thus explained that "AMPs are important sources of information because they are based on actual transaction data and represent a statutorily defined measure of average prices obtained by Sandoz for drugs distributed to the retail pharmacy class of trade" (Sandoz' Opening Motion at 5-6); and that because Medi-Cal had Sandoz' AMPs for a number of years, it had an average of "*the fully-discounted prices* received by Sandoz for drugs sold directly or indirectly to retail pharmacies." *Id.* at 6. Whether or not as a matter of policy AMPs could or should have been used for reimbursements is consequently beside the point. California had in its possession, directly from Sandoz, transaction-based averages that showed the magnitude of the AWP "spreads" it now claims were unknown.

The GPhA materials now trumpeted by California are neither relevant to nor inconsistent with this unassailable argument. Those materials address changes wrought by the Deficit Reduction Act of 2005 (the "DRA"), which changed how AMPs were to be calculated, how often they were to be reported, the level of confidentiality applicable to AMP information, and which otherwise made AMPs even more important in the federal Medicaid scheme by using them not only for payment of rebates (which had been done since 1991), but also for the determination of aggregate reimbursement limits. *See* Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,175 (proposed Dec. 22, 2006) (to be codified at 42 C.F.R. pt. 447).[5] Thus, the GPhA documents post-date the relevant time period and reflect a different regulatory structure, rendering them irrelevant. Just as importantly, they are not relevant to the point made by Sandoz' Opening Motion, namely that anyone looking at the AMPs and AWPs California had in its possession would have seen the "spreads."

Furthermore, California's asserted inconsistencies are not supported by any fair reading of the cited materials, which were prepared to address certain issues raised by the DRA's changes to the calculation and use of AMPs. In response to CMS' request for comments on its proposed implementing regulations, the GPhA submitted a February 2007 letter to CMS.[6] This letter explained the problems with using monthly averages because of the timing issues associated with normal business transactions in the industry, and explained at length how any average would be affected by the assumptions manufacturers were required to make. *See*

[5] Specifically, the DRA mandated the following changes, among others, to AMPs: (1) it required manufacturers to calculate AMPs on a monthly basis, instead of the quarterly basis used previously; and (2) it removed from the AMP calculation prompt payment discounts, which along with all other discounts were previously part of the AMP calculation. *See* Sandoz' Response to Plaintiffs' Additional SOF ¶ 13. The DRA also changed how AMPs were used and disseminated by directing CMS to calculate FULs using use AMPs, instead of compendia prices, and further directing CMS to establish regulations to implement that objective. *Id.* The DRA also directed CMS to publish AMPs so that they would be available to state Medicaid programs and others for use (or not) in reimbursement decisions, and again directed CMS to establish regulations to accomplish that mandate. *Id.*

[6] The other materials relied upon by Plaintiffs are substantively similar to this letter. *See* Sandoz' Response to Plaintiffs' Additional SOF ¶¶ 11-12, 15-18.

Sandoz' Response to Plaintiffs' Additional SOF ¶ 13. The GPhA further explained, among other things, that because AMPs condense all transactions across customers (big and small) into a single average before all related transactions have closed – again, an issue inherent in the calculation of any average in this industry – they can be misleading to someone (e.g., a consumer or payer) who has not taken the time to understand how they are calculated. *Id.* Consequently, the GPhA explained that for these reasons AMPs may not be indicative of widely-available market prices, because of the way they are calculated. Examples are included in the letter to make this clear. *Id.* Plaintiffs' arguments thus are easily rejected as they rest on a misreading of the evidence.

Plaintiffs' related argument that the "reliability" of AMPs suffers because manufacturers can restate them fares no better. Because AMPs are required to be calculated before manufacturers have all the relevant information regarding transactions (*e.g.*, final amounts for market share rebates, inventory price adjustments, and so forth), manufacturers are *required* to submit adjusted AMPs in certain instances by the terms of the Rebate Agreement.[7] *See* Sandoz' Reply SOF ¶ 8. The fact that AMPs may need to be adjusted does not affect their accuracy when calculated, or their utility for determining the magnitude of the difference between AWPs and AMPs, which was the point made in Sandoz' motion. There is nothing nefarious, discretionary or even relevant about the requirement for adjusting AMPs.

Fifth and finally, California's attempt to distinguish Sandoz' cited case law is unavailing. Plaintiffs argue for a higher standard of government knowledge than is required under the case law. Plaintiffs also seek to take each piece of evidence in isolation and dismiss it as insufficient.

[7] By contrast, the averages calculated by Plaintiffs' expert were done retrospectively, after all transactions affecting prices were known, and even then used assumptions to allocate discount and rebates across a 12 month time horizon. *See* Weedman Decl. Ex B (Expert Report of Dr. Jeffery D. Leitzinger ¶ 18). Plaintiffs' expert nonetheless testified that his averages were in the neighborhood of reported AMPs. *See* Weedman Decl. Ex. C (Transcript of Deposition of Jeffrey Leitzinger at 92:20-93:16 (Sept. 23, 2009)).

That approach is not appropriate, because it is the cumulative knowledge shown by all of the evidence that must be considered by the Court. *See United States v. Catholic Healthcare W.*, 445 F.3d 1147, 1151 (9th Cir. 2006) ("elements of the fraud allegation need not be made public in a single document"); *Dingle v. Bioport Corp.*, 388 F. 3d 209, 214 (6th Cir. 2004) ("The fact that the information comes from different disclosures is irrelevant."); *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Heahtcare Sys.*, 384 F. 3d 168, 174 n. 8 (5th Cir. 2004) (multiple sources "considered as a whole."). The undisputed facts, when viewed cumulatively, leave no doubt that California was aware of the pricing practices of Sandoz, and the nature and magnitude of the so-called "mega-spreads," such that summary judgment is warranted, because California cannot prove *scienter* (or falsity).

## II. The Three Year Period in the Statute of Limitations Applies to California's Claims

Relying on the same factual record as it did for the *scienter* argument, Sandoz' Opening Motion demonstrated that by at least 1999, there was a "perfect storm" of information reflecting Sandoz' prices in particular, and generic drug pricing in general, that would have "put reasonably prudent government officials on notice of a potential false claim." *Debro v. Los Angeles Raiders*, 92 Cal. App. 4th 940, 954-55 (2001). All the undisputed facts discussed above thus are relevant to Sandoz' motion on the statue of limitations.

The standard for this inquiry is not seriously disputed. Sandoz need not show, as California concedes, that the relevant public officials knew "every detail or determine[d] the particular legal theory the plaintiff would assert" to trigger the statue of limitation. Plaintiffs' Opposition at 15. Instead, "facts which would lead a reasonably prudent person to suspect" the false claim are sufficient. *See Debro*, 92 Cal. App. 4th at 954-55; Sandoz' Opening Motion at 10-11 (citing cases). As noted above, well prior to August 1999, California had, *inter alia*,

Sandoz' AWPs and its AMPs (and URAs), government reports that AWPs were not actual averages of wholesale prices and evidence of the difference between AWP and average generic prices at the retail level (*e.g.*, the 1996 OIG report regarding average prices available to retailers in California on generic drugs),[8] and allegations from Ven-A-Care claiming that manufacturer AWPs were fraudulent. Such evidence comfortably meets the legal standard to trigger the statute of limitations.

California's argument that there are "genuine issues of material fact regarding the extent and timing of information available to the Attorney General concerning each drug at issue in this case, and whether such information was sufficient to trigger the statue of limitations under California law" (Plaintiffs' Opposition at 15) does not withstand scrutiny.[9]

A. *California's incomplete and improper factual analysis*

As discussed above, the AMP information provided directly by Sandoz to California for 6 years (1991 to 1997) for each drug illustrated the spreads between AWP and AMPs (a measure of Sandoz' average prices at the retail level) that California now claims it did not have. The URAs for each Sandoz drug that California concededly had also provided similar information. California has no answer for these undisputed fact, and thus ignores them, claiming that Sandoz "cannot cite to any evidence" in support of its statement that "California was specifically aware of the difference between AWP and actual average transaction prices at the retail level for each

[8] California officials concededly met with the federal officials who conducted the study, as part of the preparation, design and execution of the study. Defendants' Joint SOF ¶¶ 29-31.

[9] California erroneously suggests that the "relevant public official" for statute of limitations purposes is the Attorney General. There is no such requirement, and Plaintiffs' reliance on *State of California ex rel. Hindin v. Hewlett-Packard Co.*, 153 Cal. App. 4th 307, 318 (2007), is misplaced. In fact, the Court in *Hindin* explicitly stated that the discovery must have been made by "a public official *such as* the Attorney General" (emphasis added). There is no requirement that the Attorney General itself actually make the discovery, as Plaintiffs suggest. Indeed, the Court in *Hindin* noted with approval that when drafting the relevant statute of limitations provision, the Legislature specifically stated that discovery occurred "when the violation is known *to the public agency* defrauded by the false claim." *Hindin*, 153 Cal. App. 4th at 316 (emphasis in original). As such, the relevant inquiry in the current statute of limitations analysis focuses on Medi-Cal.

and every Sandoz NDC from 1991 to 1997 and the URAs for each NDC at all other times." *See* Plaintiffs' Opposition at 16. California's position is nonsense.

California's companion statement that "only two documents are offered by Sandoz to support its statute of limitations defense" (Plaintiffs' Opposition at 16) similarly misreads Sandoz' brief, which incorporates by reference the Joint Defendants' Opening Motion's discussion regarding California's knowledge of generic drug pricing (Sandoz' Opening Motion at 1, 8 and 11), to avoid burdening the Court with duplicative briefing, a fact acknowledged at page 10 n.5 of Plaintiffs' Opposition to Sandoz. To oversimplify to make the point, the obvious thrust of Sandoz' motion is that when the undisputed facts regarding the availability of Sandoz' AMPs and URAs are combined with evidence regarding California's knowledge and understanding of drug pricing, in particular generic drug pricing, and the fraud allegations made by Ven-A-Care to California in 1998, the evidence overwhelming shows the required level of information sufficient to trigger the statue of limitations.

Thus, California's effort to try and limit the impact of the 1996 OIG Report and the 1998 Ven-A-Care *qui tam* complaint by arguing that, while these alerted Plaintiffs to *some* issues with pharmaceutical price reporting, they did not alert Plaintiffs to *every* issue, is misplaced. Again, California misstates the standard and suggests an improper approach. California does not need to know every fact necessary to bring a lawsuit, only those that would counsel a government official to make further inquiry. *Debro*, 92 Cal. App. 4th at 954-55 (holding that "[i]t is not necessary that all of the facts be discovered fro the limitations period to commence," the law "merely requires that the responsible government officials be placed on notice of the facts giving rise to the claim, not that they learn of every detail or determine the particular legal theory the plaintiff would later assert."). And the facts cannot be examined one at a time, with each one

thrown out seriatim because it alone fails to show that a reasonable government official would have been on notice to make further inquiry.

B. *California's irrelevant case law analysis.*

California finally tries to confuse the issues by arguing that this Court's prior decisions regarding statute of limitations are not relevant because those decisions either (i) resulted from trial; (ii) relied on Massachusetts law; or (iii) depended on plaintiffs carrying the burden, not defendants. California's distinctions are meritless.

First, California apparently cites to this Court's opinion in *Mylan Labs.* for the proposition that statute of limitations is not an appropriate inquiry at the summary judgment stage. *See* Plaintiffs' Opposition at 17. This Court's refusal to grant summary judgment in that case turned on the fact it needed to make a "drug-by-drug" analysis because the record was unclear when the plaintiffs were made aware of the alleged false claims. Such an ambiguity does not exist in the present case; as shown *supra*, Sandoz provided California directly with AMPs, not only on a drug-by-drug basis but on an NDC-by-NDC basis, from 1991-1997. Consequently, there is no question "what [California] should have known, and when it should have known it." *Mylan Labs.*, 608 F. Supp. 2d at 159-160.

Furthermore, California's attempt to distinguish this Court's opinion in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007), as dependent on Massachusetts law is baseless. Indeed, there is nothing inherent in the California False Claims Act that makes dismissal on statute of limitations grounds inappropriate, as Plaintiffs imply. To the contrary, as the *Debro* court held, CFCA claims that are instituted more than three years after the discovery of the alleged false claims are legally insufficient. *See generally Debro*, 92 Cal. App. 4th 940.

Finally, Plaintiffs claim that this Court's prior holdings involved situations where plaintiffs had the burden to disprove a statute of limitations, whereas here Sandoz has the affirmative burden to prove its statute of limitations defense, and further that statute of limitations questions are more appropriate questions for juries. Plaintiffs' contention is irrelevant. Sandoz, as demonstrated *supra*, has more than carried any burden it may have to demonstrate facts to trigger the limitations period. Furthermore, California's claim that a statute of limitations defense is a question of fact ignores the obvious: courts routinely dismiss statute of limitations cases on summary judgment under California law. *See, e.g., Levin v. Graham & James*, 37 Cal. App. 4th 798, 805-06 (1995) (affirming lower court's granting of summary judgment because plaintiff's claim was barred by statute of limitations); *Gray v. Reeves*, 76 Cal. App. 3d 567, 577-78 (1977) (same); *Snoke v. Bolen*, 235 Cal. App. 3d 1427, 1432-33 (1991) (same).

In sum, by at least 1999, there was such "a perfect storm of information" with respect to Sandoz which put California "on notice to investigate the possibility that AWP had become unhinged from acquisition costs causing [California] to overpay for drugs." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 78. Accordingly, California's claims are limited by the three-year statute of limitations, which bars all of California's CFCA claims against Sandoz that accrued prior to August 1999.

## CONCLUSION

For the reasons set forth above and in Sandoz' Opening Motion, Sandoz respectfully requests that the Court grant this motion.

Dated: January 15, 2010
New York, NY

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I, Jacqueline L. Chung, hereby certify that on January 15, 2010, I have caused true and correct copies of the foregoing Defendant Sandoz Inc.'s Reply in Support of its Motion for Summary Judgment to be served on all counsel of record by electronic service pursuant to the Case Management Order No. 2 entered in by Honorable Patti B. Saris in MDL 1456.

/s/ Jacqueline L. Chung
Jacqueline L. Chung